Remote Training in Evidence-based Practices for Clinicians who Work with Migrant Workers

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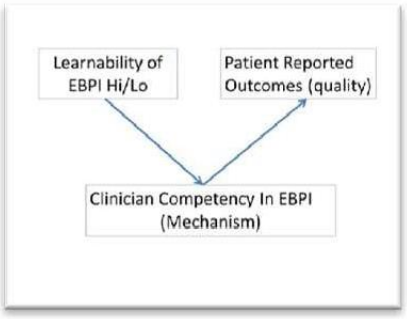
SPECIFIC AIMS. Per the Institute of Medicine (IOM) report on Psychosocial Standards, the US suffers from a dearth of clinicians who can offer evidence-based psychosocial interventions (EBPI)[1]. This limited **clinical capacity** is due to poor preparation of clinicians before they enter the workforce and variable quality of graduate and postgraduate training. The main challenge in training clinicians in EBPIs is the complexity of the interventions (Study 2), and the numerous decisional dilemmas clinicians face when using EBPIs in care (Study 3). To effectively train clinicians in EBPIs, trainees must undergo in-depth education, intensive skill building and close supervision[2]. As an example, the Increasing Access to Psychological Treatment (IAPT) clinician training program requires 6 months to one year of postgraduate training, which includes 1-2 days a week in didactics, scaffolding skill building, and close, videotape-guided supervision[3]. Thus, a major barrier to building capacity is the lack of time-efficient and educationally effective EBPI training models. Innovations in computer science and adaptive training algorithms may provide a way to train clinicians in effective use of EBPIs. Early evidence on these programs finds that they effectively reduce time in training[4], improve competence in complex decision-making and standardize training[5]. As an example, a recent study funded by the Defense Advanced Research Projects Agency (DARPA) found that an intelligent tutoring system (ITS) for naval engineers not only *reduced training time by 18 months*, but graduates of this program *were more competent that engineers who were trained traditionally and had been in the field 10 years.* Our proposed study builds on the existing research base on EBPI training, and adds to it by designing and testing a computerized training program (ITS) based on adaptive training algorithms. We hypothesize that capacity building through improved EBPI learnability (target mechanism) will result in enhanced clinical ability to deliver EBPI elements competently, in a shorter time period, and that greater competence will result in better quality of care (Fig. 2. The data from the current R34 will serve to inform a R01 proposal to test the comparative scalability, implementation costs and training effectiveness of computerized training versus training-as-usual.

Aim 1. **Discover Phase (3 months)** Using iterative and participatory methods, we will work with 10 paraprofessionals who had been trained in telephone-based cognitive behavioral therapy (tCBT) to discover challenges they face in delivery of tCBT, identify areas in the traditional curriculum that supported their skill acquisition, and areas that were missing from the training. Feedback from study team members with expertise in teaching bachelor-level students and other key stakeholders will help inform this process. This information will be used to build the adaptive algorithm in Aim 2. Contribution to the Center: Because the process of educational development includes the identification of competencies that are challenging to learn, data from this phase will be used to inform the Typology of EBPI Targets.

Aim 2. Design and Build Phase (9 months). After identifying educational modification targets, and key decisional dilemmas to be built into the program, we will build an Intelligent Tutoring System (ITS) in tCBT via rapid iterative design. The 6 trainees who participated in the *Discover* phase will be actively involved in the *Design/Build* phase, in conjunction with educational experts in tCBT. Contribution to the Center: Data from this phase will be used to inform the Matrix of EBPI Modifications.

Aim 3: **Test Phase (18 months).** We will test and compare the addition of an ITS in tCBT to training-as-usual in a small-scale randomized controlled trial. Ten to twelve students will be randomized to the two conditions. **H1**: The ITS will result in better rating of tCBT usability (AFLA-Q Acceptability, System Usability and User Burden Scales), and student confidence in using tCBT compared to traditional training. **H2:** Students randomized to the ITS will certify faster (hours in training), and will more competently deliver tCBT elements (number of sessions rated below standard by experts and time to first session rated below standard) than clinicians randomized to traditional training. **H3:** Patients treated by computer-trained students will report better outcomes on functional disability (SDS; Sheehan Disability Scale), and change in depression symptoms over time (PHQ-9 total score) than those treated with traditionally trained students. We will conduct preliminary analysis to determine if change in clinical outcomes is mediated by clinician quality.



This study addresses IOM recommendation 6-2: Infrastructure to support high-quality treatment includes ongoing provider training, and NIMH SP 4.2: Build models to scale up effective interventions for use in public and private primary care, specialty care, and other systems.

SIGNIFICANCE

1. There is a shortage of EBPI-prepared clinicians in low-resourced communities. Research indicates that ethnic minorities,[6] older adults,[7] and people living in rural areas,[8] are at greatest risk of not receiving evidence-based psychosocial intervention (EBPI), despite their preference for this treatment.[9-17] At fault are several instrumental barriers to care, such as transportation barriers,[18-20] interference with work hours (psychotherapy is typically delivered in weekly, hour-long appointments in a clinician's office),[21-27] and the stigma that many cultural groups have related to seeking care.[28,29] But of all the barriers to influence accessibility of EBPI in low-resourced communities, the most problematic are *supply-side barriers*—that is, too few EBPI-prepared clinicians living in these areas. Due to inadequate numbers of EBPI-prepared clinicians and serious geographic maldistribution, many parts of the US experience a severe shortage of mental health providers, particularly low-income and rural areas.[30] According to the recent IOM report on standards for psychosocial interventions,[31] even when therapists are available, the quality of care delivered can be substandard. Addressing the supply-side barriers has reached critical importance. As the US Preventive Services Task Force has recommended universal screening for depression,[32] healthcare organizations will be identifying far more patients with depression, in turn necessitating delivery of high-quality depression care to these patients.

2. State-of-the-art EBPI training programs are too costly and not scalable. Per the IOM Report on Standards for Psychosocial Interventions[31], few graduate training programs are preparing the workforce to delivery EBPIs. As health care organizations move toward the medical home model, and adopt integrated care programs like Collaborative Care, clinicians have to learn EBPIs in the field. This imposes considerable limitations on the time they are able to dedicate to training, as well as the effort involved in learning new interventions that were not designed for busy practices[33]. Most high quality programs use educational scaffold methods[34] (e.g., the revised Bloom's taxonomy[35]), where core competencies are first identified, then categorized into educational levels (knowledge acquisition, knowledge application, analytic skill, creativity), and teaching methods are tailored to the educational level (e.g., didactics for knowledge transfer, simulated case roleplay for knowledge application, mentored case review for analytic skill). The UK's Increasing Access to Psychotherapy Program (IAPT) clinician education program uses a scaffolding educational approach that includes didactics, simulated case rehearsal, and mentored case review (supervision) with caseloads that become increasingly complex[2,36,37]. Although a successful program, it is also a very expensive program (£33 million a year), one that many US-based primary care clinics cannot support[38,39]. The Veterans Administration and the UW AIMS Center use models like the IAPT model, with less intensity, but the success of such modified models has been variable[40]. The scalability of these programs is limited by expert time to conduct training activities[41-43], clinician time away from work to engage in training activities, training expense, and variable training quality across supervisors and trainers[41,44].

3. e-Learning and Adaptive Training has the potential to transform EBPI training for all provider levels. Innovations in electronic learning methods (e-Learning) and adaptive training programs have the potential to address the problems current training programs face. Adaptive learning is an educational method which uses adaptive computerized algorithms to tailor the presentation of educational material per trainees' learning needs, based on initial assessments, experience and in-training task performance. The technology encompasses fields of study including computer science, education, psychology, and neuroscience. The need for these programs arose from the observation that tailored education is difficult to deploy, to scale, using traditional, non-adaptive training approaches. Adaptive learning programs relevant to EBPI training are **intelligent tutoring systems** (ITS). ITS are computerized programs that guide trainees through simulated cases, decisional dilemmas and other higher order cognitive tasks, and provide immediate and customized instruction and feedback to the trainee[45-47]. ITS is particularly beneficial in cases where there are too few trainers available. Recent research shows that these systems have the capacity to train novices in high level problem solving, at times to better competency than seasoned experts,[45] and that training times to reach competency can be significantly reduced. For example, Dr. Popovic (co-PI and adaptive education expert) has found that children who use adaptive training were able to learn complex algebraic concepts (7th grade content) in 1.5 hours, and could complete algebraic solutions with nearly 100% accuracy[48-51]. Using dynamic specialization the same study showed that these effects can be achieved by over 80% of elementary school students in multiple state-wide trials. Similar results for ITS systems are found in various fields of medicine[52-55], but have yet to be applied to mental health (see Innovation for further details).

***4.* Study Purpose.** Using our Center's *Discover, Design/Build, and Test* (DDBT) framework, we will create—in close collaboration with former paraprofessionals who were trained traditionally in telephone-based CBT (tCBT)—an Intelligent Tutoring System (ITS) for tCBT. We will compare this approach to traditional education plus roleplay training on perceived usability of tCBT post training, clinician time to certification, skill drift over time, and patient-reported outcomes. *Why focus on telephone-based CBT?* Preliminary evidence finds that CBT is an effective treatment for depression in Latino populations. We recently demonstrated that versions of tCBT are not only acceptable, but are effective interventions for rural Latinos suffering from depression[56-58]. *Why focus on rural Latinos?* Latinos face barriers in the accessibility, availability and provision of mental health services. While they are more likely than the general US population to use primary care settings as their source of behavioral health care,[9,10] psychotherapy is rarely available to them, particularly in rural communities[59,60 61-66]. Among Mexican Americans, the largest subgroup of Latinos in the country and in our state, only a third with depression receive any care, and only 12% receive care concordant with practice guidelines[67-72].

5. Impact. Our program enables trainees to learn from local and national experts while maintaining connections to their culture, context, and support system. Developing the program with local support and expertise, embedding the program in a rural university, Heritage University (HU), treating patients of local primary care clinics, and recruiting students from HU, optimizes the program's sustainability[59] and improves community capacity.[61] Through this proposed study's processes of *discover, design/build and test* of our curriculum and training program, we respond to the importance of training non-degree personnel emphasized by the Annapolis Coalition on the Behavioral Health Workforce[23, 24].Such paraprofessionals can play an important role in expanding mental health care in primary care[73] and rural settings[74]. Also, we address the need noted by the IOM[75] and the President's New Freedom Commission on Mental Health[76] to improve quality and access to mental health care by increasing the numbers of trained ethnic minority providers.

INNOVATION

The main innovation from this R34 is in the use of adaptive training models to build clinical competencies in paraprofessionals working with low-income, rural Latino patients. Our program builds on past efforts to use computerized training in two ways (1) by including the experiences of past trainees in building the curriculum as well as its features (e.g., computerized avatars versus real patient scenarios), and (2) by using game-based algorithms that utilize behavioral psychology principles to enhance educational engagement. We will test whether this program is successful at building a much-needed workforce in a short time period, while building provider effectiveness in the use of tCBT, and thus generate a workforce of paraprofessionals who are competent in tCBT. A challenge in training paraprofessionals is largely in the need for on-going, intensive supervision. We will evaluate whether adaptive training will result in better sustained skill and lower need for intensive supervision. We point out here that the work we are proposing is a novel ITS for training in EBPIs, and is different from the work on Virtual Patients. The use of Virtual Patients (patient simulations using video game technology) has preliminary evidence for effectively training social work students in mental health assessment[77-79]. Current versions of Virtual Patients use locked-in algorithms to assess—rather than train—specific skills, where all trainees start at the same place in the simulated case interaction, with minimal adaptation. Furthermore, Virtual Patients are only one avenue for training competencies in mental health. An innovation in our study is that, using our DDBT framework, we will create an intelligent tutoring system that is adaptive and includes a variety of competency building exercises that are more than simulated interactions (see Phase 2/Aim 2 below). Additionally, we intend to build an EBPI ITS that is easily deployed with minimal costs. Current market based virtual patient simulations expensive and have limited evidence base.

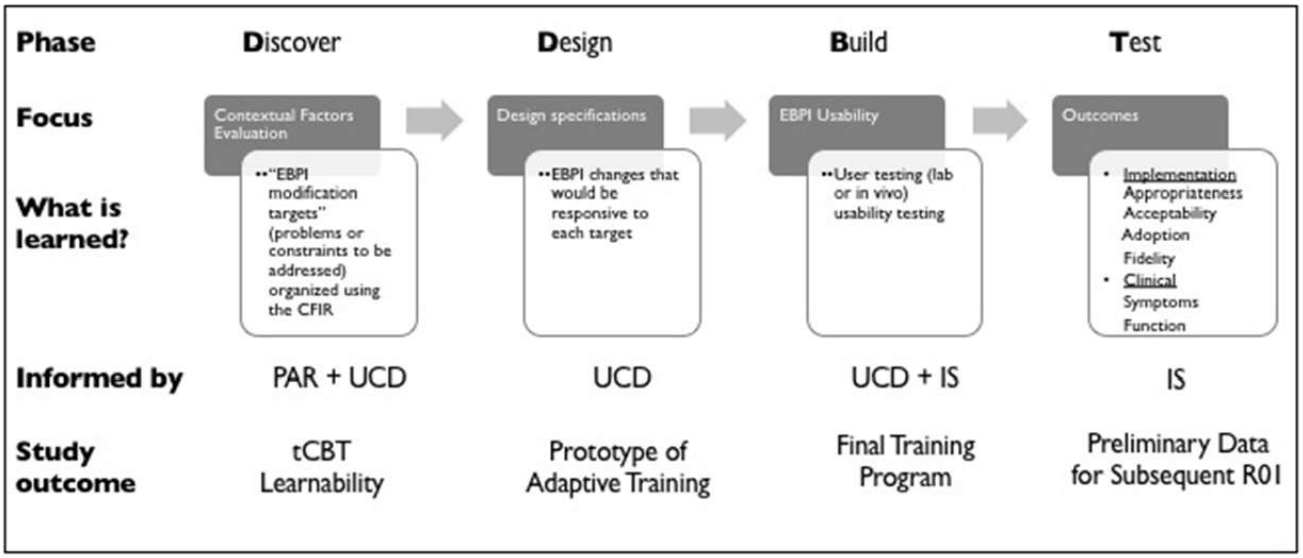
APPROACH

Team Expertise and Preliminary Studies. This proposal focuses on best strategies for training paraprofessionals in implementing telephone based psychotherapy in rural primary care settings serving Latino populations by a community-academic partnership firmly responsive to community-based participatory research (CBPR) principles and values. This proposal builds on study team experience, including: 1) training novice ethnic minority and bilingual students in manualized cognitive behavioral therapy (CBT), 2) implementing telephone-based depression interventions, 3) expertise in computer-directed training, and 4) participatory action research (PAR), enabling us to deepen an existing authentic and impactful community-academic partnership informed by PAR values and framework. Dr. Aiesenberg is a noted expert in training clinicians in EBPIs. In a previous randomized pilot study which adapted manualized tCBT[80] for rural, low-income Latinos[81], we trained and supervised 5 Latino bilingual therapists, ranging from recent Master of

Social Work (MSW) graduates to experienced MSW therapists. Dr. Popovic is a noted expert in the use of adaptive training algorithms for the creation of intelligent tutoring systems, educational games, and e-Learning platforms. He currently leads the team that produced *Foldit*, a biochemistry game that develops novice users into problem-specific experts capable of solving protein-folding dilemmas that stump professional biochemists[82]. Recently, his neuroscience discovery game enabled novices to speed up the neuron 3D reconstruction process by a factor of four when compared to the state-of-the-art expert reconstructions. The same techniques are now deployed in mathematics and English language digital curricula targeting struggling learners in 26 states. His contributions to the field of computer graphics have been recently recognized by several awards including the NSF CAREER Award, Alfred P. Sloan Fellowship and the Association for Computing Machinery (ACM) SIGGRAPH Significant New Researcher Award.

Training program in telephone-based CBT (tCBT). tCBT consists of 8 sessions delivered over 10 to 12 weeks. Each session is designed for delivery in 35 - 40 minutes and includes: structured assessment of depressive symptoms (5 min); review of prior session content (5 min); debriefing previous homework assignment (5-10 min); introduction of new material, including in-session examples and exercises (15-20 min); description of the new homework assignment (5-10 min); and a motivational assessment/enhancement exercise focused on the homework assignment (5 min). The current tCBT training program has four key elements: 1) training program content, designed to target competencies of knowledge and attitude, competence in delivering CBT, and fidelity to the treatment; 2) teaching methods, targeting both the cognitive domain (principles and guidelines needed to deliver EBPI) and the affective domain (attitudes and values related to EBPI); 3) simulated case training to practice skills; and (4) teachers and supervisors to provide on-going skill building with actual patients.

Figure 1. DBBT Model for Research Study.



Study Overview. To accomplish the aims of the study, this project will be broken down into 3 phases that are tied to each aim of the study: *the Discover phase*, (Aim 1), *the Design and Build phase* (Aim 2), and *the Test phase* (Aim 3; see Fig. 1. For phases 1 and 2, we will work with 10 paraprofessionals who have been trained in tCBT using the traditional mode described above. For phase 3, we will recruit 2 successive cohorts of 5-6 bachelor students from Heritage University and randomize them to the traditional training model and the new adaptive learning method. The study will be conducted over a 2.5 year period during Y01 through Y03. Steps 1 and 2 will be conducted in the first 9 months of the study and Step 3 in the last 15 months (See timeline).

Phase 1/Aim 1: Discovery (3 months). The purpose of this phase is to identify key competencies and decisional dilemmas trainees experience when learning tCBT. Drs. Aisenberg and Popovic will be responsible for data collection and synthesis in this phase. As is detailed in the **Methods Core**, *Discover* phase data collection involves the identification of user needs, contextual evaluation, and user testing.

Identification of user needs. We will conduct semi-structured interviews with 10 formally tCBT certified paraprofessionals. The interview will interrogate challenges they face in implementing tCBT that are related to key tCBT core competencies. We will ask them to provide examples of where they have struggled using tCBT and how a training program could prepare new paraprofessionals for these challenges. Questions will be tied to the Consolidated Framework for Implementation Research (CFIR) constructs related to intervention and individual characteristics (see **Methods Core**). We will also ask about modifications and accommodations the clinicians have made tCBT.

Contextual evaluation. We will review audio sessions and evaluation forms from past paraprofessional trainings to identify common challenges and errors made while providing tCBT. This information will help to further identify key decisional dilemmas and implementation challenges that adaptive training may address. Observations will be guided by CFIR as well as Bloom's revised taxonomy (see **Methods Core**), and will include observations of inner and outer settings and how they potentially influence the training in tCBT.

User Testing. We will work with students who have recently graduated been trained in tCBT. Because the paraprofessionals in this study have already undergone traditional training, they have participated in a form of user testing. We will interview the trainees and go over the educational materials and simulated case roleplays they engaged in when training. They will engage in a think-aloud exercise; while going over the training materials, they will provide us with their impressions, what they recall of their initial reaction to materials and training experiences, and how competent they felt with tCBT after the training.

Data Synthesis and Confirmation of Findings. Recordings of interviews will be transcribed and entered in to Atlas.ti, a qualitative data analysis and research software, to organize data for coding by multiple coders. A codebook will be created to describe data codes and meaning of codes. Interviews will be coded by the qualitative methods support available from the Center's Methods Core. Coding will be grounded in the CFIR constructs as well as Bloom's revised taxonomy[83] to inform learning objectives for each educational level. As interviews are coded, the results will be reviewed by the coders to discuss findings, resolve discrepancies, and identify any new themes. The final product from this data synthesis will be a training program guide that includes the arrangement of core competencies by level of difficulty, types of educational strategies to train the competencies, and branching algorithms to inform computerized skill-building scenarios. Data collected on the challenges faced by paraprofessionals in using tCBT will be given to the Methods Core directors for use in the development of the Typology of EBPI Targets**.** Although the focus of target identification in this phase is in the challenges in the implementation of tCBT for training purposes, we anticipate that these targets would be informative for projects focused on EBPI usability modifications (e.g.: Study 2) and EBPI sustainability solutions (e.g.: Study 3).

Phase 2/Aim 2 Design and Build Phase (9 months). The next step in the process will be to create initial educational prototypes and the adaptive algorithm for the ITS based on the findings in the *Discover* phase. Because of the engineering demands required to build these programs, the Methods Core will hire an additional programmer and a computer science graduate student to work with Dr. Popovic. The original 10 students who were involved in the discovery phase will participate in the user design and testing steps as detailed below. The process will follow these steps:

Conduct a semantic content breakdown of the curriculum and key competencies. Data from the *Discover* phase is critical to accurately breaking down the curriculum into micro-concepts and their dependencies, annotating tCBT competency challenges and tying them to the micro-concepts, analysis of variation within the curriculum and designing different educational and computational scaffolds for each educational step. Dr. Aisenberg and the former students will participate in this process with Dr. Popovic and his team. This process then leads to an initial adaptive method that assesses trainee skill for a given problem and then creates an educational scaffold for the student that is tailored to his/her needs. For example, by observing data logs of learner behavior, the system may determine that a specific micro-concept (e.g.,agenda setting) is an appropriate proximal learning target for an individual based on already mastered prerequisite micro-concepts. The semantic content breakdown enables micro-concept training to follow multiple paths for a student ranging from full explicit explanation (standard instruction), to partially worked example (practice problem with some aspects explained while others left for student to do), to dynamic fading-away of supports within a worked example leading to increased independence and mastery.

Create interactive prototypes of educational exercises targeting different tCBT competencies. During trainee interaction with these exercises, we will use a pragmatic "discounted usability engineering" approach where we will observe them as they work through the prototypes while thinking aloud. This involves a rapid series of individual user tests with slight modifications between observations until a satisfying solution is achieved or the approach is abandoned. As an example, while training paraprofessionals in competent review of CBT action plans with patients, they may be presented with different types of simulated patient interactions. These may include virtual telephone patients that paraprofessionals interact with as if they were talking to the patient; a text-based simulated patient, where the paraprofessional may be asked to respond to different scenarios that evolve and change depending on the interaction; an observation-based simulated case, where actual sections of paraprofessional and patient interactions are presented at different points in the conversation, and the trainee is asked to provide the best response to an a patient's comment. Each one of these training components are further parameterized to provide a much broader spectrum of practice problems that vary the level of ambiguity and difficulty, level of scaffold support, need to leverage prerequisite concepts, etc.

Incorporate training algorithms into the program that engage the trainee and challenge them in a productive manner (Productive Struggle). This step does not involve end-users. Ideally, the training algorithm should be set at a 70% "win" rate, where 70% of the interactions are at the trainee's level of competence, and the remaining are above their level. These win rates are common in educational games, where the program or game needs to be somewhat challenging, but not so challenging that the trainee becomes frustrated. These win rates are also adaptive and change as the trainee become more proficient. Rapid, real-time feedback of observable improvement is also key to engagement and trainee agency. In addition, more powerful effects in productive struggle can be generated by allowing students to focus on their effort, being able to examine multiple hypothesis, and persisting through challenging problems. This focus on process rather than success rate has been shown to significantly increase time-on-task and overall drive of students in digital learning environments.

Data driven refinement of the adaptive algorithm. This step requires rapid diagnostics, diagnostic proxies, or embedded diagnostics to discover gradient of improvement for each trainee. Data collected from the 10 trainees as they interact with the system provides information to the algorithm to improve its ability to maintain productive struggle and accurately advance trainees to more complex competencies. For example, based on data feedback, the adaptive methods can determine the optimal level of scaffolding support provided to trainees once the system determined a weakness along a specific competency. Although our trainee sample size is too small to create truly adaptive trainings, the data we collect here will serve as proof-of-concept for full-scale deployment that will automatically and continuously improve as each trainee group interacts with the program. Refinement in a small sample like ours can be augmented with peer or tutor-observed evaluation of the trainee performance that is dynamically entered the system. The final product will be used in the *Test* phase.

Phase 3/Aim 3: Test Phase (18 months). We will conduct a pilot study comparing the tCBT training that includes the ITS program (from the *Design/Build* phase) to the traditional training program and its impact on time to learning tCBT and competency delivering tCBT. Latino bachelor-level social work and nursing students from Heritage University will be invited in the Spring quarter of their junior year to apply to participate in our specialized program. We will randomize 10-12 students in years 1 and 2 (two successive cohorts of 5-6 students each) during the study and each will work with five patients using tCBT

Patient eligibility. Sixty patient participants will be identified through Yakima Valley Farmworker's Clinic electronic health record. Participants must be 18 years old or older, suffering from mild to moderate depression with PHQ-9 scores of 10-20. Identified patients will be contacted by a Methods Core research assistant to conduct a preliminary screening for eligibility, provide a brief description of the study and obtain informed consent.

Paraprofessional Data Collection. After training, paraprofessionals will be assigned a total of 5 cases each to assess paraprofessional capacity to conduct tCBT. Two types of data will be collected—paraprofessional

assessment of tCBT usability, and ability to learn tCBT and maintain competency. To measure **intervention usability**, paraprofessionals will complete the ALFA-Q[84] Acceptability Scale, the User Burden Scale (UBS) [85] and the System Usability Scale (SUS) [86], which are core measures for this center (see **Methods Core** for description of scales). These scales will be collected through the UWAC data portal after initial training in tCBT after they have seen their 5th patient. **Learnability** of the tCBT will be measured as time to reach competency during training. To measure **sustained competency,** paraprofessionals will collect audio recordings of patient sessions for review by experts. Drs. Aisenberg and Raue will conduct these reviews using the Cognitive Therapy Scales (CTS)[87] adapted to apply to structured, manualized telephone CBT. The CTS utilizes a 7-point rating scale (0 = *poor*, 6 = *excellent*) and has been used to assess the competence of paraprofessional therapists[63]. Sustained competency will be defined by (1) time to first session rated below average and (2) number of sessions rated below average.

Patient data collection. We will use the UWAC data portal[88] designed specifically for research on mobile depression interventions to confirm eligibility, complete the consent process, and conduct baseline and outcomes assessment. Participants will receive $20 for completing each of 2 (baseline and post treatment assessments. Patient data will be collect before treatment initiation and after treatment ends.

Patients will complete a demographic survey to determine gender, age, ethnicity, income categories, and education. Patients will complete a series of brief clinical measures to determine the presence of a depressive disorder and if there are any important comorbidities. The *Sheehan Disability Scale (SDS)* [89,90] is a brief analog scale measuring functioning in work, social, and health domains, using visual-spatial, numeric and verbal anchors. This scale has been validated in medical and psychiatric populations with a variety of psychiatric diagnoses.[89,90]. The *9-item Patient Health Questionnaire*[91] *(*PHQ-9) consists of 9 DSM depression symptoms and one disability item. It has been found to have excellent sensitivity to change over time, with good sensitivity (88%) and specificity (88%) for major depression using a PHQ-9 score ≥10.[92]

Data Analysis. Aim 3 focuses on pilot feasibility data to inform a larger (future) clinical trial comparing ITS-based training in tCBT to training-as-usual (TAU). Thus, analyses do not focus on hypothesis-driven inferential statistics but on descriptive statistics, graphical summaries, and basic effect sizes. H1: Usability. Differences in clinician-reported usability between ITS training and TAU will be plotted using a dotplot and tested using a *t*-test using the ALFA-Q, SUS, and UBS as dependent variables. H2: Fidelity/Competence: A similar strategy (dotplot, *t*-test) will be used with number of hours to reach certification. Number of sessions with CTS scores in competent range will be summarized as proportions, both by clinician and by treatment. Between-group differences will be tested with a 2-sample proportion test. (Future analyses with larger sample size will use a generalized linear mixed model approach to account for the nested data[93,94].) H3: Patient-Reported Outcomes. Histograms and kernel density estimates will be plotted by treatment condition to explore differences on depression outcomes (PHQ-9 total score) and overall daily functioning (SDS). Descriptive statistics (*M* and *SD*) will also be examined by clinician and by treatment, using Cohen's *d* as an effect size summary. A *t*-test will be used to examine treatment differences in patient outcomes. Of ultimate interest is whether the modified training protocol (i.e., ITS vs. TAU) has its impact on patient outcomes through enhanced learnability via clinician competence/fidelity. We will use graphical summaries of the data to explore the relationships that are consistent with mediation (e.g., correlation of usability with patient outcomes [b pathway], and treatment differences on patient outcomes with fidelity partialed out [c' pathway']). The primary focus here is whether the data and relationships appear consistent with mediation, as opposed to a formal test, which will be dramatically under-powered.

Power and Sample Size. Sample sizes for Aims 1 and 2 were based on estimates from the user-centered design literature on necessary number of participants to capture critical design information, where the recommendation is 5-10 end users. Aim 3 is focused on gathering information (feasibility, recruitment and retention rates, response and attrition rates, etc.) for a future R01 application. Thus, the sample size was set primarily for practical reasons and driven by estimated effect sizes rather than hypothesis testing..

Timeline. This study will begin in Y02 of the Center. The *Discover* phase activities will be completed in 3 months. The Design/Build phase will be completed in 9 months. The *Test* phase will take 18 months, of which identification and training of clinicians in the two interventions will take approximately 2 months for each cohort. Patient recruitment and data collection will take 10 months. Data analysis will take 3 months.

HUMAN SUBJECTS

Overview:

We have developed procedures to *minimize risk* to our participants and to create conditions that make study participation as *comfortable as possible*. To this end, data collection for all phases of the study will be conducted at Heritage University (Discovery Phase) and through the virtual prototype portal/sandbox. For phase 3 activities, patients will also be participants providing data. Data collection on outcomes will be collected through the UWAC Data portal. These and other measures developed have led to high retention rates and participant satisfaction in our previous randomized clinical trials.

This is a three-phase study. Trainee participants in the Discover (first) phase and Design/Build Phase (second) will not be the same trainee participants in the Test (third) phase. However, recruitment, participant characteristics, consenting, and assessment protocols will be the same for all three study phases. Study phase specific human subjects concerns will be highlighted in each section below.

Human Subjects Involvement, Characteristics, and Design

Clinician Participants. For phase 1 and 2, we will recruit participants from the former trainees in the Heritage University tCBT program. For Phase 3, trainee participants will be newly enrolled trainees.

Inclusion/Exclusion**.** For phases 1 and 2, we will identify 6 trainees who have been certified in tCBT. For phase 3, clinicians will all be tCBT naïve.

Patient Participants. In phase 3, patients will be recruited from the Yakima Valley Farm Workers Clinc. The site champion will identify participants through electronic health records, contacting those with a PHQ-9 of >10 and ascertain interest in participation.

Inclusion Criteria

1. Age 18+ years.

2. PHQ-9 > 10.

3. Capacity to provide written consent for both research assessment and treatment._E

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1. Intent or plan to attempt suicide in the near future.

2. History or presence of psychiatric diagnoses other than unipolar, non-psychotic major depression or generalized anxiety disorder.

3. Acute or severe medical illness, i.e., delirium, metastatic cancer, decompensated cardiac, liver or kidney failure, major surgery, stroke or myocardial infarction during the three months prior to entry.

Clinician Informed Consent. In all three phases of the study, clinicians will be provided informed consent. A member of the UWAC Methods Core will contact the clinicians, review study procedures, and answer any questions and concerns. Participants will be told they are volunteers and may discontinue at any time.

Patient Informed Consent.

Patients who are identified through electronic health records with a PHQ-9 > 10 will be contacted by a local site champion in appropriate methods of recruitment and informed consent to discuss the project with the patient and determine whether or not they are interested. We chose to have staff from the clinical site obtain initial consent because patients are likely to be more comfortable talking with someone from their community who can describe the study in a culturally appropriate manner. In addition, because patients are likely to have an ongoing relationship with staff they will be more comfortable asking questions and expressing potential concerns about study participation. All staff engaged in research will complete CITI Human Subjects Protection Training and will then receive training from the PIs regarding the appropriate procedures for recruitment and consent. The training will cover: 1) choosing a location; 2) determining capacity to consent; 3) explaining the study in easy to understand language. We will also make it clear to staff the consequences of coercing patients into participating in the study. Staff who are found to be coercing patients to participate will be removed from the study protocol. After initial consent is obtained, the person is given an authentication code that to login to

UWAC data portal. These authentication codes make it difficult for people to log on pretending to be the participant. Staff at the sites will provide disclosure about what is involved in the study including the potential risks and benefits. We will develop a Frequently Asked Questions sheet so that participants have accurate answers to all questions and up to date contact information for the PI and Co-PI and the IRBs if the participant wants to obtain additional information about the study. The informed consent process will culminate by the person choosing whether or not to sign the informed consent document; once they do, they can select a unique, cryptographic passcode that will only work for that person. If signed, a copy will be made and given to the participant and the original will be sent to the UWAC staff.

Sources of Materials.

Patients. Phase 3 enrolled patients will complete an online survey in English or Spanish at baseline and post treatment. Clinic staff and UW staff will have access to participant identifiers (e.g. patient name, email, address, alternative contact information) for the purpose of reaching the participant to complete the baseline survey, to follow-up with them for post treatment surveys and to pay them for completed surveys. Surveys will be conducted the UWAC data portal that directly enters responses into an electronic dataset, eliminating paper forms that might get lost or misplaced. The electronic dataset will be stored on UW's Amazon Web Services HIPAA Compliant server. Participant data is automatically sent to the AWS secure server behind established university firewalls via custom, encrypted API calls in JSON format. A MongoDB database is used to capture all data, with access only through administrator privileges that require a unique username and password. Specific summary data extracted from the JSON is also written in parallel to a MySql database for additional summary statistics used to populate participant-specific dashboards to provide an ongoing view of their progress in the study.

Phase 1 and 2 data. Qualitative interviews regarding their experience with the training program will be conducted via interactive video and be audio recorded. The UWAC discovery team will have access to provider identifiers (e.g. provider name, phone number) for the purpose of scheduling interview. Voice recordings are considered identifying information and the transcriptionist will have access to this for purposes of creating a transcript for analysis.

Audio Recordings. Audio recordings of participant and clinician interaction in Phase 3 to study clinician competency will be uploaded to a HIPAA-compliant FTP (file transfer protocol) server at the University of Washington (UW) so that they can be reviewed. This system is password protected and each recording has a designated recipient and only that person can access it. The system is further designed to automatically delete recordings after a pre-determined number of days if not accessed so they do not linger on the system. Once the recordings are reviewed UWAC staff will insure that no identifiable information remains on the transcript before analysis.

Potential Risks.

The primary risk of participating in this proposed study is loss of confidentiality due to the inadvertent release of sensitive information. Steps will be taken to prevent this risk, and the procedures to be taken if it does occur are described in detail below. Another potential risk is respondent burden during the online research surveys. Based on our prior use of the survey instruments, we do not expect the assessments to present substantial burden to respondents. The baseline assessment is expected to take no more than 20 minutes and the follow-up interviews take no more than 15 minutes. If respondents become fatigued or distressed during their assessment, they can complete it later. Based on the prior experience with similar studies examining depressive symptoms, we believe that the instances of participants becoming emotionally distressed due to the survey process will be minimal.

Protection of Confidentiality. All study staff will be trained by the UWAC Methods Core on the protection of participants' rights, especially in areas relevant to confidentiality. All staff will acknowledge in writing that they will abide by the University's rules and procedures pertaining to the rights of participants, confidentiality, and

data safety in general. They will acknowledge that any lapse could result in disciplinary action or termination. In addition, the proposed project will adhere to the following general rules of data safety: 1) all staff will sign a written commitment to maintain an atmosphere of confidentiality, which will include not discussing confidential study information with anyone outside the study team and not attempting to learn the identity of an individual participant; 2) all data will be marked only by a non-identifying ID number; 3) all identifying information (consent forms, contact information for follow-up interviews) will be kept separate from data gathered from participants and kept in password-protected files in password-protected computers or systems; 4) non-study personnel will at no time be permitted to view identifying information; 5) all electronic data containing identifiers will be maintained with password protection, 6) all participants must understand, agree, and sign a consent for before participating and will be provided a copy of the consent form with instructions about how to contact a university official responsible for research oversight with any questions or concerns; 7) strict adherence to a participant's right to withdraw or refuse to answer questions will be maintained; and 8) participants will be provided with a summary of study results upon verbal or written request. In addition, qualitative interviews will be scheduled ahead of time to facilitate participant privacy in case friends or family members (who may be unaware that the individual is participating in a study) may be curious as to why the participant is being contacted. We will train research assistants to tactfully avoid answering such questions. ***For student participants:*** Data from this study will not be shared with university or clinic staff. Performance as tCBT clinician, and performance during training will be handled as usual, through supervision, but will not influence student grades.

Data Security. Consent forms will have the e-signature of the participant. Locator forms will contain the participant's name, study ID, clinic patient ID, current address and emails, as well as the addresses and telephone numbers of contacts. For survey data, each study participant will be given a unique, but non-identifying number. No names or other identifying information will appear in the data. Electronic copies of the research data will be kept on the password-protected server which is backed up nightly. Electronic copies of the questionnaire responses will be kept indefinitely to insure the ability to replicate analyses. Audio recordings will be transmitted to the transcriptionist via a HIPAA-compliant FTP server and recordings will be transcribed with removal of as much personally identifiable information as possible. Once the transcriptions are confirmed to be accurate, the audio recordings will be destroyed. Electronic copies of the transcriptions will only be available to members of the study team, and will be stored on a password-protected computer server that is housed in a locked facility with restricted access.

UWAC data portal, the online portal that will be used for assessment, is housed at UW Department of Psychiatry and Behavioral Sciences. The portal follows HIPAA's data security standards (as detailed here: http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/techsafeguards.pdf). Specifically, we follow their requirements for the four technical safeguards or 1) access control (e.g., we have unique user identification and policies for emergency access detailed in our consent form); 2) audit controls (i.e., our data is able to be audited); 3) integrity (e.g., we use logic checks to ensure data integrity); 4) person authentication (e.g., we require participants to login into their emails to authenticate their identity before granting them a username) and 5) transmission security (e.g., limits transmission of data whenever possible, but if necessary, we de-identify the data prior to transmission or will encrypt identifiable data). All systems are secured behind the UW firewall and follow UW Information Security policies for authenticated, minimum access. All systems are patched, monitored and scanned routinely for vulnerabilities and intrusions by the systems administrator and AWS Information Security. The web server and database server are hosted within the UW AWS Firewall. The web server makes use of 128-bit secure socket layer encryption to protect data in transit. The Data Core is experienced in data management for multicenter clinical studies and utilizes the following data security measures: (1) Data Transmission: The web server (provisioned by AWS) currently utilizes 128-bit secure socket layer (SSL) encryption to protect data in transit; (2) Antivirus Software: All servers run up-to-date anti-virus software; (3) Firewall: The network, including all the servers that will store UWAC data, is behind a secure firewall that does not allow unauthorized access to any research data server. At this time, we are not aware of any limitations with our data security plan, but we do recognize that no data management system is 100% secure.

Distress and Acute Suicide Risk. Although this is a mild to moderately depressed population, suicidality could be a potential concern. The clinical staff on this project (site therapists) will all be trained to manage when they detect suicidal ideation, and research assistants monitoring the PHQ-9 scores from the BRIGHTEN portal will be educated on what to do when someone has a score of 1 or greater on the 9th item of the PHQ. Participants will be instructed that they can terminate the study at any point.

Potential Benefits of the Proposed Research to Human Subjects and Others. Although the study is designed to improve quality and outcomes of care, there is no guarantee that study participants will receive any clinical benefits by participating in the study.

CLINICAL TRIALS.GOV REQUIREMENTS

This study qualifies as an "Applicable Clinical Trial" according to U.S. Public Law 110-85. We will register this protocol on www.ClinicalTrials.gov.